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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,002	01/07/2005	Sean Mark Dalziel	CL2101USPCT	4855

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Wilmington, DE 19898

EXAMINER

VETERE, ROBERT A

ART UNIT	PAPER NUMBER
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1792

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12/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,002	Applicant(s) DALZIEL ET AL.	
	Examiner ROBERT VETERE	Art Unit 1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-14 and 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-7, 9-13, 16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Handjani et al. (US 6,203,802) in light of Fujiura et al. (US 5,002,986) and further in light of Lech (US 5,681,577).

Claims 1 and 5-7 and 16: Handjani teaches a method of coating nanoparticles with a size of 10-1000nm (3:1-3) with polyunsaturated fatty acids (3:36-50) wherein the fatty acids on the loaded particles are 60 wt% or greater (3:55-58) to produce a particle useful in pharmaceutical treatment (Abst.). Handjani fails to teach the steps of claim 1, but teaches that the nanoparticles may be coated by any known process (4:32). Fujiura teaches a method of coating particles comprising high intensity mixing of liquids with fine particles in a fluid mixer by suspending the fine particles in a turbulent gas stream and contacting the particles with a liquid sprayed from a pressurized nozzle (6:54-66). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the nanoparticles of Handjani using the method of Fujiura with the predictable expectation of success because Handjani explains that any known method may be used to coat the nanoparticles.

Handjani and Fujiura fail to teach that the nanoparticles are silica. Lech, however, teaches a method of producing coated silica particles useful as drug release devices (2:45-55) and that silica is useful as a carrier material because it masks the bitter taste of the drug delivery device (2:45-55). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used silica as the carrier particle in Handjani in order to have masked the bitter taste of the coated drug delivery device.

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Claims 3-4: Handjani also teaches that the coating composition may be aqueous or non-aqueous (3:59-65).

Claims 9-13 and 19-20: Lech also teaches that sweeteners are added to the coated nanoparticles in order to improve their taste (3:60-4:15). While Lech does not explicitly teach sucrose as the sweetener, sucrose is well known in the art as a sweetener. Furthermore, with respect to the method used to deposit the sweetener as a coating liquid or as a liquid encapsulating material, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the method of Fujiura because it is the method which is already being used to coat the nanoparticles in the first step of the combined method of Handjani and Fujiura.

With respect to the limitations “coating liquid” and “liquid encapsulating material,” according to applicant’s specification, on page 5, a sweetener qualifies under both of these categories.

With respect to the addition of a sweetener, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated a sweetener, such as sucrose, as taught by Lech, into the combined method of Handjani and Fujiura in order to improve the taste of the drug delivery device.

3. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Handjani, Lech and Fujiura in light of Barnhart et al. (US 5,762,952).

Claim 8: Handjani and Fujiura fail to teach that the coating process is repeated. However, Barnhart teaches that it is known in the art to repeat coating processes on pharmaceutical devices in order to obtain a coating with a desired thickness (8:5-7). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have repeated the steps of claim 1 in order to have obtained a coating with a desired thickness.

4. Claims 1, 5-7, 9-14, 16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni (US 3,921,636) in light of Fujiura and Lech.

Claims 1, 7, 14, 16 and 18: Zaffaroni teaches a method of forming nanoparticles having a size of 5-7 nm (see, e.g., 12:61-62) useful as drug release devices (Abst.) which can be loaded using any known technique (7:47-48). Fujiura teaches a method of coating particles comprising high intensity mixing of

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liquids with fine particles in a fluid mixer by suspending the fine particles in a turbulent gas stream and contacting the particles with a liquid sprayed from a pressurized nozzle (6:54-66). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated the nanoparticles of Zaffaroni using the method of Fujiura with the predictable expectation of success because Zaffaroni explains that any known method may be used to coat the nanoparticles.

With respect to claim 14, Zaffaroni also teaches that the drug delivery device is a free flowing microcapsule (claimed dry flowable powder; see, e.g., 13:43-45).

Zaffaroni and Fujiura fail to teach that the nanoparticles are silica. Lech, however, teaches a method of producing coated silica particles useful as drug release devices (2:45-55) and that silica is useful as a carrier material because it masks the bitter taste of the drug delivery device (2:45-55). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used silica as the carrier particle in Zaffaroni in order to have masked the bitter taste of the coated drug delivery device.

Claims 5-6: Zaffaroni teaches that the nanoparticles are coated with essential fats useful as pharmacologically active agents (11:36-40).

Claims 9-13 and 19-20: Lech also teaches that sweeteners are added to the coated nanoparticles in order to improve their taste (3:60-4:15). While Lech does not explicitly teach sucrose as the sweetener, sucrose is well known in the art as a sweetener. Furthermore, with respect to the method used to deposit the sweetener as a coating liquid or as a liquid encapsulating material, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the method of Fujiura because it is the method which is already being used to coat the nanoparticles in the first step of the combined method of Zaffaroni and Fujiura.

With respect to the limitations “coating liquid” and “liquid encapsulating material,” according to applicant’s specification, on page 5, a sweetener qualifies under both of these categories.

With respect to the addition of a sweetener, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated a sweetener, such as sucrose, as taught

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by Lech, into the combined method of Zaffaroni and Fujiura in order to improve the taste of the drug delivery device.

5. Claims 6 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni, Lech and Fujiura in light of Rubin (US 4,961,936).

Claim 6: Zaffaroni teaches that the nanoparticles are coated with essential fats useful as pharmacologically active agents, but fails to expressly teach that these essential fats are polyunsaturated fatty acids. However, the examiner takes official notice that polyunsaturated fatty acids, such as EPA and DHA, are well known in the art as pharmacologically active essential fats (see, e.g., Rubin, US 4,961,936 at 5:17-20).

Claim 17: Zaffaroni, Fujiura and Lech fail to teach what type of polyunsaturated fatty acid is used. However, both EPA and DHA are well known in the art as pharmacologically active essential fats (see, e.g., Rubin at 5:17-20). The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected EPA and DHA as the polyunsaturated fatty acids used in the combined method of Zaffaroni, Fujiura and Lech.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni, Lech and Fujiura in light of Barnhart.

Claim 8: Zaffaroni and Fujiura fail to teach that the coating process is repeated. However, Barnhart teaches that it is known in the art to repeat coating processes on pharmaceutical devices in order to obtain a coating with a desired thickness (8:5-7). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have repeated the steps of claim 1 in order to have obtained a coating with a desired thickness.

Response to Arguments

7. Applicant's arguments filed 10/16/2008 have been fully considered but they are not persuasive.

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Applicant argues that Handjani, Fujiura and Zaffaroni fail to teach that the carrier substrate is selected from one of the materials described in the amended portion of claim 1. The examiner agrees with this argument.

Applicant further argues that the combination of Zaffaroni, Fujiura and Lech teach all the limitations of amended claim 1. Specifically, applicant asserts that because Lech teaches a method that removes water from the coated particle, Lech teaches away from applicant's claimed invention. This is not persuasive. Lech, as described above, teaches the benefit of replacing an organic carrier with a silica carrier as the carrier substrate in a drug delivery device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated this teaching from Lech into the combined method of Zaffaroni and Fujiura because they also teach a method of forming a drug delivery device and the motivation provided by Lech would have given one of ordinary skill in the art at the time the invention was made adequate reason to make the combination. The fact that Lech teaches that water is removed has no bearing on its teaching that silica is useful as a carrier material because it masks the bitter taste of the drug delivery device.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT VETERE whose telephone number is (571)270-1864. The examiner can normally be reached on Mon-Fri 9-6.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Cleveland can be reached on 571-272-1418. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Vetere/
Examiner, Art Unit 1792

/Michael Cleveland/

Supervisory Patent Examiner, Art Unit 1792